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Comparative Study of Open Hemorrhoidectomy and Rubber Band Ligation in the Treatment of Third-Degree Hemorrhoids

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ABSTRACT

Hemorrhoids, commonly known as piles, are vascular structures in the anal canal crucial for maintaining continence. When swollen or inflamed, they can significantly impact quality of life. The global prevalence of hemorrhoids varies, with notable rates in Australia (38.93%), Israel (16%), and Korea (14.4%). In the U.S., about 10 million individuals experience symptomatic hemorrhoids annually. Hemorrhoids are categorized into four grades, with third-degree hemorrhoids representing prolapsed hemorrhoids requiring manual reduction. Among treatment options, open hemorrhoidectomy and rubber band ligation are prominent. Open hemorrhoidectomy is effective but associated with postoperative pain and extended recovery. Rubber band ligation is less invasive with faster recovery but may be less effective for larger hemorrhoids. A comparative interventional study was conducted at Santosh Medical College and Hospital, Ghaziabad, over one year. The study included 88 patients aged 18-65 years with third-degree hemorrhoids, randomized into two groups: Group A (open hemorrhoidectomy) and Group B (rubber band ligation). Pain on postoperative day (POD) 1 was measured using the Visual Analogue Scale (VAS). Data on hospital stay, postoperative complications, and wound healing were collected on POD 7, 30 and 60. Statistical analysis was performed using SPSS version 17. The median pain score on POD 1 was significantly higher in Group A (8) compared to Group B (2) (p=0.001). The median hospital stay was longer for Group A (6.5 days) compared to Group B (0 days) (p=0.001). On POD 7, pain was reported by 25% of Group A and 18.2% of Group B (p=0.559). By POD 60, wounds had healed in all patients in both groups. At 6 months, recurrence was 4.5% in Group A and 11.4% in Group B (p=0.237). Rubber band ligation offers advantages in reduced postoperative pain and shorter hospital stays compared to open hemorrhoidectomy, though it may have a higher recurrence rate. The choice of treatment should be tailored to individual patient needs. Further research is needed to confirm these findings and assess long-term outcomes.

INTRODUCTION

Hemorrhoids, commonly referred to as piles, are vascular structures located in the anal canal that play a crucial role in maintaining continence. When these structures become swollen or inflamed, they can cause significant discomfort and distress, impacting an individual's quality of life. The global prevalence of hemorrhoids is estimated to be around 4.4%, though this rate varies significantly across different regions and countries. Notably higher prevalence rates have been reported in countries such as Australia (38.93%), Israel (16%) and Korea (14.4%), whereas data from Africa is limited, indicating a gap in understanding the burden of this condition in that region . In the United States, approximately 10 million individuals experience symptomatic hemorrhoids annually[1]. The etiology of hemorrhoids is multi factorial, involving increased intra-abdominal pressure, straining during bowel movements and genetic predisposition[2]. Hemorrhoids are categorized into four grades based on severity, with third-degree hemorrhoids representing prolapsed hemorrhoids that require manual reduction. These hemorrhoids pose a unique challenge in terms of treatment options and patient management. Consequently, the management of hemorrhoids has gained increasing attention in the medical field, prompting researchers to explore various treatment modalities to alleviate symptoms and improve patient outcomes[3,4]. Among the various treatment modalities, open hemorrhoidectomy and rubber band ligation have emerged as prominent options for managing third-degree hemorrhoids . Open hemorrhoidectomy, first described by Milligan and Morgan in 1937, involves the excision of hemorrhoidal tissue through a conventional surgical incision. This procedure is considered the gold standard for treating advanced hemorrhoidal disease, especially third-degree hemorrhoids, due to its benefits of complete removal of prolapsed tissue and a low recurrence rate . However, open hemorrhoidectomy is associated with certain drawbacks, including postoperative pain, extended recovery time and risks of complications such as bleeding and anal stenosis[5]. Rubber band ligation, a less invasive outpatient procedure, involves placing a rubber band around the base of the hemorrhoidal tissue to cut off its blood supply, leading to necrosis and eventual sloughing off. This technique is widely employed for treating second-and third-degree hemorrhoids and is associated with lower postoperative pain and faster recovery compared to open hemorrhoidectomy. Although studies have demonstrated the effectiveness of rubber band ligation in achieving symptomatic relief and reducing the recurrence of hemorrhoids, concerns have been raised about its efficacy in treating larger or thrombosed hemorrhoids[6]. The choice between open hemorrhoidectomy and rubber band ligation is critical in the management of third-degree hemorrhoids. Understanding the nuances of each procedure is crucial for tailoring treatment plans to individual patient needs. Open hemorrhoidectomy, while effective in providing long-term relief, is associated with a relatively higher risk of postoperative pain, longer recovery times and potential complications. On the other hand, rubber band ligation, with its quicker recovery and less invasive nature, may have limitations in terms of efficacy and the possibility of recurrence .

Aims: To analyze and compare various peri-operative factors in patients suffering from third-degree hemorrhoids undergoing conventional hemorrhoidectomy and rubber band ligation.

Objectives:

- To evaluate the cost-effectiveness, number of days off work and time taken for recovery between the two procedures.
- To assess post-operative comfort for patients using the Visual Analogue Scale (VAS) on post-operative day (POD) 1.
- To compare post-operative complications, including immediate (pain, bleeding, prolapse, discharge, incontinence and urine retention) and long-term complications (recurrence and stricture of the anal canal).

MATERIALS AND METHODS

Study Setting: The study was conducted in the Department of General Surgery, Santosh Medical College and Hospital, Ghaziabad.

Study Duration: One year (November 2022 to November 2023).

Study Design: Comparative interventional study.

Sample Size: According to Mushtaq A. Gagloo (9) et al study, considering the proportion of Rubber Band ligation shows no prolapse as 50% and proportion of haemorrhoidectomy shows no prolapse as 87.5% at 95% confidence interval with 95% power, the sample size is calculated as

$N = (Z1\text{-}a/2 + Z1\text{-}ß)\ 2 * 2 * p * (1\text{-}p) / (p1\text{-}p2)^2$

Z1-a/2-two tailed probability for 95% confidence interval=1.96

Z1-ß - two tailed proabability for 95% power =1.64

p1 (%)-proportion of Rubber Band ligation shows no prolapse =0.5

p2 (%) - proportion of haemorrhoidectomy shows no prolapse =0.88
p-Average prevalence of Rubber Band ligation shows no prolapse and Hemorrhoidectomy shows no prolapse=0.69.
N = (1.96 + 1.64) ^2 * 2 * 0.69 * (1 - 0.69) ^2 / (0.5 - 0.875) ^2
N=39.71 round off to 40
Thus the sample size required for each group is 40 and the total sample size is 80
Assuming 10% non-responsive rate which is 8
Total sample size + non responsive rate - 80+8 = 88
The final sample size is 44 patients in each group and the total sample size is 88 patients.

Study Participants:
Inclusion Criteria:
- Patients willing to participate in the study.
- Patients aged 18-65 years suffering from third-degree hemorrhoids.

Exclusion Criteria:
- Patients refusing to participate.
- Patients younger than 18 or older than 65 years.
- Patients with first- or second-degree hemorrhoids or prolapsed hemorrhoids.
- Patients with suspected malignancy.
- Patients with established HIV, Hepatitis infection, or chronic liver disease (CLD).
- Patients with a history of previous ano-rectal surgery.
- Patients unfit for surgery.

Groups:
- **Group A:** Treated with Open Milligan-Morgan Hemorrhoidectomy.
- **Group B:** Treated with Rubber Band Ligation.

Sampling Technique: Patients were randomly assigned to one of two groups using a computer-generated random number code, with allocation concealed by the Serially Numbered Opaque Sealed Envelope (SNOSE) method.

Data Collection: Data were collected by the principal investigator using structured questionnaires. Informed written consent was obtained from all participants. Detailed histories and thorough clinical examinations were conducted, including digital rectal examination, proctoscopy and when indicated, colonoscopy. Baseline investigations included CBC, KFT, blood sugar, urine examination, chest X-ray and ECG.

Methodology:
Group A: Open Milligan-Morgan Hemorrhoidectomy The hemorrhoidal tissue was removed in a radial pattern, leaving cutaneous and mucosal edges without suture. Adequate bridges were left between excisions to prevent anal stenosis. The procedure was performed under spinal or saddle anesthesia.

Group B: Rubber Band Ligation Performed in lithotomy position using McGivney forceps ligator through an anoscope. Rubber bands were deployed tightly around the base of the internal hemorrhoids, ensuring placement above the dentate line to avoid somatically innervated tissue.

Pain Measurement: Pain was measured using the Visual Analogue Scale (VAS) on POD 1.

Statistical Analysis:
- Data entry was performed using Microsoft Office Excel 2013 and analysis was done using SPSS software version 17.
- Shapiro-Wilk test was used to check for normal distribution.
- Continuous variables following normal distribution were expressed as mean and standard deviation; those not following normal distribution were expressed as median and inter quartile range.
- Categorical variables were described using frequency and proportion.
- Independent sample T-test, Chi-square test and Mann-Whitney U test were used for significance testing, with a p-value <0.05 considered statistically significant.

Ethical Considerations: Ethical approval was obtained from the Institutional Ethical Committee (approval no. SU/2022/3108[21]). Confidentiality and ethical principles such as respect for patients, beneficence, and justice were strictly adhered to throughout the study.

RESULTS AND DISCUSSIONS

This table presents the demographic and clinical characteristics of participants undergoing conventional hemorrhoidectomy and rubber band ligation. The age distribution shows a higher concentration of participants aged over 45 in both groups. The mean age for conventional hemorrhoidectomy was 45.93±11.47 years and 45.27±10.95 years for rubber band ligation, with no significant difference (p=0.783). The majority of participants were male (76.1%). The chief complaints included mass per rectum (77.3%), painful defecation (50%), constipation (71.6%) and bleeding per rectum (21.6%). Proctoscopy findings varied, with the most common being a mass at 3 o'clock (29.5%). Increased anal tone was observed in 80.7% of participants and 65.9% were non-vegetarian (Table 1).

Table 1: Demographic and Clinical Characteristics of Study Participants

Characteristics	Conventional Hemorrhoidectomy	Rubber Band Ligation	p-value
Age (years)			
- 18-30	4 (9.1%)	6 (13.6%)	
- >30-45	18 (40.9%)	15 (34.1%)	
- >45-65	22 (50%)	23 (52.3%)	
- Mean±SD	45.93±11.47	45.27±10.95	0.783
Gender			
- Male	67 (76.1%)		
- Female	21 (23.9%)		
Chief Complaints			
- Mass Per Rectum	68 (77.3%)		
- Painful Defecation	44 (50%)		
- Constipation	63 (71.6%)		
- Bleeding Per Rectum	19 (21.6%)		
Proctoscopy Findings			
- Mass at 11 o'clock	13 (14.8%)		
- Mass at 3 and 7 o'clock	13 (14.8%)		
- Mass at 3 o'clock	26 (29.5%)		
- Mass at 3, 7 and 11 o'clock	9 (10.2%)		
- Mass at 7 and 11 o'clock	6 (6.8%)		
- Mass at 7 o'clock	21 (23.9%)		
Per-Rectal Examination Findings			
- Increased Anal Tone	71 (80.7%)		
- Normal Anal Tone	17 (19.3%)		
Diet			
- Vegetarian	30 (34.1%)		
- Non-Vegetarian	58 (65.9%)		

Table 2: Pain Score and Hospital Stay

Variable	Conventional Hemorrhoidectomy	Rubber Band Ligation	p-value
Pain Score on POD 1 (VAS)			0.001
- Median	8	2	
- Interquartile Range	1	1	
- Minimum	5	1	
- Maximum	9	4	
Duration of Hospital Stay (days)			0.001
- Median	6.5	0	
- Interquartile Range	2	0	
- Minimum	4	0	
- Maximum	10	1	

Table 3: Post-Operative Complications on POD 7, 30 and 60

Complications	Conventional Hemorrhoidectomy	Rubber Band Ligation	Total	p-value
POD 7				
- Pain	11 (25%)	8 (18.2%)	19	0.559
- No Complications	29 (65.9%)	33 (75%)	62	
- Incontinence	3 (6.8%)	1 (2.3%)	4	
- Discharge	1 (2.3%)	2 (4.5%)	3	
POD 30				
- No Complaints	38 (86.4%)	43 (97.7%)	81	0.116
- Anal Incontinence	3 (6.8%)	0	3	
- Anal Stricture	3 (6.8%)	1 (2.3%)	4	
POD 60				
- No Complaints	41 (93.2%)	43 (97.7%)	84	0.359
- Anal Incontinence	2 (4.5%)	0	2	
- Anal Stricture	1 (2.3%)	1 (2.3%)	2	

Table 4: Wound Healing Status on POD 7, 30 and 60

Wound Healing Status	Conventional Hemorrhoidectomy	Rubber Band Ligation	Total	p-value
POD 7				
- Not Healed	11 (25%)	6 (13.6%)	17	0.177
- Good	33 (75%)	38 (86.4%)	71	
POD 30				
- Not Healed	4 (9.1%)	2 (4.5%)	6	0.398
- Good	40 (90.9%)	42 (95.5%)	82	
POD 60				
- Not Healed	0	0	0	-
- Good	44 (100%)	44 (100%)	88	

Table 5: Long-term Follow-up at 6 Months

Follow-up at 6 Months	Conventional Hemorrhoidectomy	Rubber Band Ligation	Total	p-value
Complaints				
- Reoccurrence	2 (4.5%)	5 (11.4%)	7	0.237
- No Complaints	42 (95.5%)	39 (88.6%)	81	

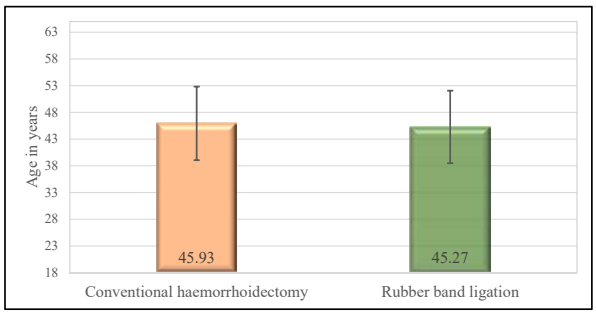

Fig. 1: Error Bar Diagram Shows Age Distribution Among Study Participant

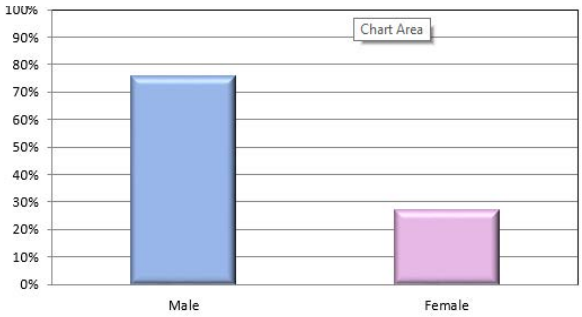

Fig. 2: Cluster Bar Diagram Shows Gender Distribution Among Study Participants

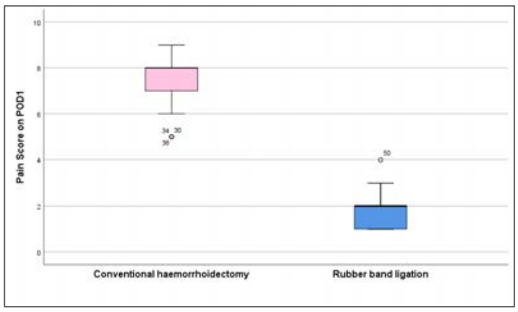

Fig. 3: Error bar Diagram Shows Pain Score Distribution on Post-Operative day 1 Among Study Participants

This table compares pain scores and duration of hospital stay between the two treatment groups. On the first postoperative day (POD 1), the median pain score for conventional hemorrhoidectomy was significantly higher (median 8) compared to rubber band ligation (median 2), with a p-value of 0.001. The duration of hospital stay was also longer for conventional hemorrhoidectomy, with a median of 6.5 days compared to 0 days for rubber band ligation, again with a significant p-value of 0.001 (Table 2). This table summarizes post-operative complications at POD 7, 30 and 60. On POD 7, pain was reported by 25% of conventional hemorrhoidectomy patients and 18.2% of rubber band ligation patients (p=0.559). No complications were observed in 65.9% and 75% of the respective groups. By POD 30, 86.4% of conventional hemorrhoidectomy and 97.7% of rubber band ligation patients had no complaints (p=0.116). By POD 60, 93.2% of conventional hemorrhoidectomy and 97.7% of rubber band ligation patients had no complaints (p=0.359) (Table 3). This table details the wound healing status at POD 7, 30 and 60. By POD 7, wounds had healed in 75% of conventional hemorrhoidectomy patients and 86.4% of rubber band ligation patients (p=0.177). By POD 30, 90.9% of conventional hemorrhoidectomy and 95.5% of rubber band ligation patients had good wound healing (p=0.398). By POD 60, all patients in both groups had fully healed wounds (Table 4). This table examines the long-term outcomes at 6 months post-procedure. Recurrence of hemorrhoids was observed in 4.5% of conventional hemorrhoidectomy patients and 11.4% of rubber band ligation patients (p=0.237). The majority of patients reported no complaints, with 95.5% in the conventional hemorrhoidectomy group and 88.6% in the rubber band ligation group (Table 5).

Hemorrhoids are a common condition that can significantly impact quality of life, often requiring surgical intervention for third-degree hemorrhoids. This study compares the outcomes of conventional hemorrhoidectomy and rubber band ligation in treating third-degree hemorrhoids, focusing on patient demographics, clinical presentation, procedural findings, pain scores, hospital stay duration, post-operative complications and wound healing status.

Age Distribution: The mean age of participants in both treatment groups was similar, with no statistically significant difference. The majority of participants were between 45 and 65 years old, consistent with previous studies that have shown a higher prevalence of hemorrhoids in older age groups. This similarity suggests that age is not a critical factor in choosing between these treatment modalities.

Gender Distribution: The gender distribution was also similar between the groups, with a majority of participants being male, aligning with previous research indicating a higher prevalence of hemorrhoids in males . However, contrasting findings from a study by Hong[10] indicated a higher prevalence of hemorrhoidal disease among females, particularly

parous women . This discrepancy highlights the need for further research into gender-specific prevalence and treatment efficacy.

Duration of Hospital Stay: Patients who underwent rubber band ligation had significantly shorter hospital stays compared to those who had conventional hemorrhoidectomy. This aligns with research indicating that minimally invasive procedures like rubber band ligation are associated with shorter hospitalization and faster recovery[11-16].

Post-operative Day 7 Complaints: The distribution of complaints on post-operative day 7 was similar between the groups, suggesting comparable short-term outcomes. The lack of significant difference in post-operative day 7 complaints between the two treatment groups supports the notion that both modalities are associated with acceptable short-term outcomes[17,18].

Healing Status on Post-operative Day 7: The wound healing status on post-operative day 7 was similar between the groups, indicating comparable early postoperative healing. Post-operative Day 30 Complaints and Healing Status. Both groups had similar distributions of complaints and wound healing status on post-operative day 30, suggesting comparable long-term outcomes . Overall, this study's findings are consistent with previous research on the efficacy and safety of conventional hemorrhoidectomy and rubber band ligation. Rubber band ligation offers advantages in terms of reduced postoperative pain and shorter hospital stays, making it a preferred treatment option for many patients. However, individual patient characteristics and preferences should guide the choice of treatment. Further research with larger sample sizes and longer follow-up periods is necessary to validate these findings and explore long-term outcomes such as recurrence rates.

Limitations: The study's limitations include a relatively small sample size and being conducted at a single center, which may introduce bias and limit generalizability. Additionally, the follow-up period was short and long-term outcomes were not assessed.

CONCLUSION

In conclusion, while traditional surgical options like open hemorrhoidectomy remain effective, minimally invasive techniques such as rubber band ligation provide promising alternatives with potential benefits in terms of reduced pain and faster recovery. This comparative study highlights the importance of evaluating different treatment approaches to optimize patient outcomes in managing third-degree hemorrhoids. Further research is essential to confirm these findings and inform clinical practice.

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